

213202.00361

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
James SAMSOONDAR, et al. ) Examiner: K. Brown  
Application No.: 10/056,205 ) Group Art Unit: 2877  
Filed: January 28, 2002 )  
For: METHOD AND APPARATUS FOR )  
MEASURING ANALYTES IN BLOOD ) February 20, 2004  
BAGS )

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MAIL STOP PETITIONS  
Commissioner for Patents  
P.O. Box 1450  
Alexandria VA 22313-1450

MAY 19 2004

FEB 25 2004

OFFICE OF THE SPECIAL  
PROGRAMS EXAMINER

**CORRECTED REQUEST FOR WITHDRAWAL OF  
ERRONEOUS NOTICE OF ABANDONMENT**

Sir:

On December 16, 2003, Applicants submitted a Request for Withdrawal of Erroneous Notice of Abandonment which incorrectly stated in the opening paragraph thereof that the reason for abandonment was for failure to pay the Issue Fee. As reflected in the rest of that document and the included attachments, the Notice of Abandonment incorrectly stated that Applicants failed to respond to an outstanding Office Action. Applicants hereby submit this Corrected Request for Withdrawal of Erroneous Notice of Abandonment to clarify the record.

Based on the facts provided below, Applicants submit that the Notice of Abandonment issued November 18, 2003 for failure to respond to an outstanding Office Action was erroneously issued by the U.S. Patent and Trademark Office.

A. On July 23, 2003, an Amendment was filed in the above-identified application in response to the Office Action mailed April 23, 2003.

B. On November 18, 2003, a Notice of Abandonment was mailed. The Notice indicates that no reply was received in response to the Office Action mailed

April 23, 2003. The Notice also indicates that Attorney Richard P. Bauer informed the Examiner on November 17, 2003 that this case was abandoned. Such an indication was in fact given to the Examiner, but the indication was made in error. Mr. Bauer called the Examiner back later on that same day (November 17, 2003), and indicated that the case was not abandoned. The Examiner informed Mr. Bauer that the Notice of Abandonment had already been mailed, and could not be recalled.

Copies of these papers are attached hereto.

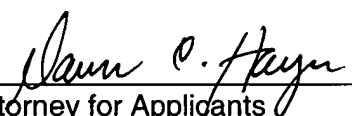
### **CONCLUSION**

Based on the above facts, and the attached documentation in support of the facts, Applicants submit that the Notice of Abandonment issued by the U.S. Patent and Trademark Office on November 18, 2003 was in error. Applicants respectfully request that the holding of abandonment for failure to timely file a reply to the April 23, 2003 Office Action be withdrawn.

As this application was abandoned because of an error by the Patent Office, no fee is believed necessary to revive this application.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address below.

Respectfully submitted,

  
Attorney for Applicants  
Dawn C. Hayes  
Registration No. 44,751

Patent Administrator  
KATTEN MUCHIN ZAVIS ROSENMAN  
525 West Monroe Street  
Suite 1600  
Chicago, Illinois 60661-3693  
Facsimile: (312) 902-1061

Applicant: Sci. Conder et al.

Appln No: 10/056,205

Filing/Issue Date: 1/23/02

Docket No: 2002-00361

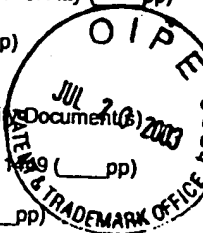
Atty/Sec: D. Hayes

Title: Method and Apparatus for Measuring Analytes in Blood Bags

Date Hand Carried to USPTO: 7/23/03

Due Date: 7/23/03

- ☒ Transmittal Form (1 pp)
- ☐ Patent Application Transmittal Form (\_\_\_ pp)
- ☒ Fee Transmittal, in duplicate (1 pp)
- ☐ Application Data Sheet (\_\_\_ pp)
- ☐ Specification (including claims & abstract) (\_\_\_ pp)
- ☐ Drawings \_\_\_ Formal \_\_\_ Informal (\_\_\_ sheets)
- ☐ Submission of Drawings (\_\_\_ pp)
- ☐ Request for Approval of Drawing Changes (\_\_\_ pp)
- ☐ Combined Oath/Declaration & Power of Atty (\_\_\_ pp)
- ☐ Declaration (\_\_\_ pp)
- ☐ Assignment with PTO-1595 (\_\_\_ pp)
- ☐ Non-Publication Request (\_\_\_ pp)
- ☐ Claim for priority (\_\_\_ pp)
- ☐ with certified copies of \_\_\_ Prior Art Documents (\_\_\_ pp)
- ☐ Sequence Listing and diskette
- ☐ Information Disclosure Stmt w/PTO 1599 (\_\_\_ pp)
- ☐ with \_\_\_ cited references
- ☐ Provisional Appln. Cover Sheet (\_\_\_ pp)
- ☐ RCE/CPA Transmittal (\_\_\_ pp)
- ☐ Response to Missing Parts w/copy of Notice (\_\_\_ pp)
- ☒ Amendment/Response (8 pp)
- ☐ with Petition for \_\_\_ Month Extension of Time
- ☐ Other: \_\_\_\_\_
- ☐ Affidavit(s)/Declaration(s) (\_\_\_ pp)
- ☐ Petition (\_\_\_ pp)
- ☐ Notice of Appeal (\_\_\_ pp)
- ☐ Appeal Brief (orig. plus 2) (\_\_\_ pp)
- ☐ Issue Fee Transmittal (\_\_\_ pp)
- ☐ Revocation of Power of Attorney (\_\_\_ pp)
- ☐ 3.73(b) Statement (\_\_\_ pp)
- ☐ Power of Attorney (\_\_\_ pp)
- ☐ Status Inquiry (\_\_\_ pp)
- ☐ Terminal Disclaimer (\_\_\_ pp)
- ☐ Request for Cert. of Correction w/PTO 1050 (\_\_\_ pp)
- ☐ Maintenance Fee Trans (\_\_\_ pp)
- ☐ Fee Address Form (\_\_\_ pp)
- ☐ Other: \_\_\_\_\_
- ☐ Other: \_\_\_\_\_
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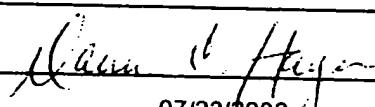
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MAY 19 2004

OFFICE OF THE SPECIAL  
PROGRAMS EXAMINER

<h1>TRANSMITTAL FORM</h1> <p>(to be used for all correspondence after initial filing)</p>	Application Number	10/056,205	
	Filing Date	01/28/2002	
	First Named Inventor	James SAMSOONDAR	
	Group Art Unit	2877	
	Examiner Name	K. Brown	
Total Number of Pages in This Submission		8	
		Attorney Docket Number	213202.00361

ENCLOSURES (check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input checked="" type="checkbox"/> Amendment / Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Assignment Papers (for an Application) <input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation <input type="checkbox"/> Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____	<input type="checkbox"/> After Allowance Communication to Group <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input type="checkbox"/> Other Enclosure(s) (please identify below):
Remarks <div style="border: 1px solid black; height: 40px; width: 100%;"></div>		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Dawn C. Hayes Registration No.: 44,751
Signature	
Date	07/23/2003

CERTIFICATE OF MAILING			
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Washington, DC 20231 on this date: <span style="border: 1px solid black; display: inline-block; width: 100px; height: 15px;"></span>			
Typed or printed name			
Signature		Date	

# FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$ ) 0.00

## Complete if Known

Application Number 10/056,205  
Filing Date 01/28/2002  
First Named Inventor James SAMSOONDAR  
Examiner Name K. Brown  
Group Art Unit 2877  
Attorney Docket No. 213202.00361

## METHOD OF PAYMENT (check all that apply)

☐ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☒ Deposit Account

Deposit Account Number

50-1710

Deposit Account Name

KATTEN MUCHIN ZAVIS ROSENMAN

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

## FEE CALCULATION

### 1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1001 750	2001 375	Utility filing fee
1002 330	2002 165	Design filing fee
1003 520	2003 260	Plant filing fee
1004 750	2004 375	Reissue filing fee
1005 160	2005 80	Provisional filing fee

Fee Paid

SUBTOTAL (1) (\$ )

### 2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims 8 -20\*\* = 0 x 0.00 = 0.00  
Independent Claims 2 -3\*\* = 0 x 0.00 = 0.00  
Multiple Dependent 0 = 0.00

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ ) 0.00

\*\*or number previously paid, if greater; For Reissues, see above

## FEE CALCULATION (continued)

### 3. ADDITIONAL FEES

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920	1804 920	Requesting publication of SIR prior to Examiner action	
1805 1,840	1805 1,840	Requesting publication of SIR after Examiner action	
2251 110	2251 55	Extension for reply within first month	
1252 410	2252 205	Extension for reply within second month	
1253 930	2253 465	Extension for reply within third month	
1254 1,450	1254 725	Extension for reply within fourth month	
1255 1,970	2255 985	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,300	2453 650	Petition to revive - unintentional	
1501 1,300	2501 650	Utility issue fee (or reissue)	
1502 470	2502 235	Design issue fee	
1503 630	2503 315	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 750	2809 375	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810 750	2810 375	For each additional invention to be examined (37 CFR § 1.129(b))	
1801 750	2801 375	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

\*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ ) 0.00

## SUBMITTED BY

Name (Print/Type) Dawn C. Hayes  
Registration No. (Attorney/Agent) 44,751  
Telephone 202-625-3549  
Signature *Dawn C. Hayes*  
Date 07/23/2003

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213202.00361

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
JAMES SAMSOONDAR, ET AL.	:	Examiner: K. Brown
	)	
Application No.: 10/056,205	:	Group Art Unit: 2877
	)	
Filed: January 28, 2002	:	
	)	
For: METHOD AND APPARATUS FOR	:	
MEASURING ANALYTES IN BLOOD	:	July 23, 2003
BAGS	)	

Commissioner for Patents,  
P.O. Box 1450  
Alexandria VA 22313-1450

**AMENDMENT**

Sir:

In response to the Office Action mailed April 23, 2003, please amend the  
above-identified application as follows:

**IN THE CLAIMS:**

Please amend the claims to read as shown below:

1. (Currently Amended) A method for determining a concentration of at least one, or more than one analyte in a sample contained in a blood bag or in a tubing in fluid communication with said blood bag, using an instrument comprising at least one, or more than one calibration algorithm for said at least one, or more than one analyte, said method comprising:

- a) irradiating said sample in said tubing, or said blood bag, using a radiation source of about 475 nm to about 2,700 nm;
- b) measuring an absorbance ~~from~~ of said sample ~~for said at least one analyte~~; and
- c) calculating a concentration of said at least one, or more than one analyte using said absorbance and said at least one, or more than one calibration algorithm.

2. (Currently Amended) The method of claim 1, wherein ~~in~~ said step of calculating (step c)) comprises ~~combines~~ determining values of first derivatives of at least two, or more than two portions of a spectrum generated from said ~~absorbance~~ step of measuring (step b), and incorporating said first derivatives into said one, or more than one calibration algorithm to provide said concentration.

3. (Original) The method of claim 1 wherein said blood bag, or said tubing is translucent and contains writing on its surface and irradiation is transmitted through said writing, said blood bag or said tubing, and said sample contained in said blood bag or said tubing.

4. (Original) The method of claim 1 wherein said step of irradiating (step a)) includes reflecting radiation from a reflective surface placed behind said blood bag or said tubing.

5. (Original) The method of claim 2 wherein in said step of measuring (step b)), light leakages are compensated for by measuring dark current for both sample and reference measurements.

6. (Currently Amended) The method of claim 2, wherein ~~the at least~~ said one, or more than one analyte is selected from the group consisting of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobin.

7. (Currently Amended) The method of claim 6, wherein in said step of measuring (step b)) ~~said absorbance measurement for said at least one, or more than one~~ analyte is incorporated into an algorithm selected from the group consisting of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue, and cross-linked haemoglobin, ~~and a combination thereof, and said concentration of said one, or more than one analyte in said sample is determined.~~

8. (Currently Amended) A method for determining a concentration of one, or more than one of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobin in a sample contained in a blood bag or in a tubing in fluid communication with said blood bag, using an instrument comprising one, or more than one calibration ~~algorithms~~ algorithm for each of said haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobin, said method comprising:

- a) irradiating said sample in said tubing or said blood bag using a radiation source of about 475 nm to about 2,700 nm;
- b) measuring an absorbance ~~from~~ of said sample, ~~for said one, or more than one of haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked haemoglobin;~~ and
- c) calculating a concentration for one, or more than one of said haemoglobin, bilirubin, biliverdin, equivalent intralipid, methylene blue and cross-linked



~~haemoglobin using haemoglobin by said absorbance and said one or more calibration algorithms, by combining~~ determining values of first derivatives of at least two, or more than two portions of a spectrum generated from said absorbance step of measuring (step b), and incorporating said first derivatives into said one, or more than one calibration algorithm to provide said concentration.

**Remarks**

Reconsideration and allowance of the subject application are respectfully requested.

Claims 1-8 are pending in this application, with Claims 1 and 8 being independent. In this Amendment, Claims 1-2 and 6-8 have been amended. All amendments are being made for reasons of clarity with respect to the specification and drawings, and not for reasons relating to the statutory requirements for patentability.

**Rejections under 35 U.S.C. 102**

Claims 1-8 stand rejected under 35 U.S.C. 102 (e) as being anticipated by Fodgaard (U.S. Patent No. 5,817,007). Applicant respectfully traverses this rejection for the reasons set forth below.

Fodgaard discloses a method of determining the concentration of a blood constituent that involves extracting a stream of blood, at a flow rate of 50-1,000 ml/min, and directing this whole blood stream through a flow-through measuring cuvette having an optically transparent surface part, and then irradiating the optically transparent surface part of the flow-through measuring cuvette with multi-wavelength near infrared (NIR) light. This is followed by detecting, and quantifying the concentration of the blood constituent. (See, for example, Col. 1, line 66 to Col. 2, line 22.)

The method of Fodgaard differs from the presently claimed method for at least the reason that it involves irradiating a stream of blood within a *flow-through* cuvette (see item 24 in Figures 1, 4 and 14; or item 90 in Figures 5 and 6). In Col. 8, lines 41-43, it is stated that the cuvette "constitutes a central or essential component of the whole blood analyzing apparatus." This method does not detect constituents of blood located within a blood bag, or within tubing in fluid communication with the blood bag, as set forth in the present claims. Furthermore, there is no teaching or suggestion

within Fodgaard that a blood bag, or tubing in fluid communication with a blood bag, can be used in place of a flow-through cuvette.

The methods claimed in Claims 1-8 are therefore novel in view of Fodgaard, and Applicant respectfully requests that the rejection under 35 U.S.C. 102(e) be withdrawn. Furthermore, Applicant submits that the features of at least Claim 1 are also not suggested in Fodgaard, and that one of skill in the art would not have been directed to the methods presently claimed upon reading Fodgaard as there is no suggestion that the flow-through cuvette may be replaced with the blood bag or associated tubing. Therefore, it is submitted that Claim 1, and dependent Claims 2-8, are also not obvious in view of Fodgaard.

Claims 1-4 and 6-8 stand rejected under 35 U.S.C. 102(b) as being anticipated by Bonner (U.S. Patent No. 4,522,494). Applicant respectfully traverses this rejection for the reasons set forth below.

Bonner discloses a method for determining the platelet concentration in plasma contained in a transfusion bag by producing a periodic laminar flow within the blood bag to assist in orienting the platelets and allowing the platelets to become randomized, followed by irradiating the sample with a HeNe laser and measuring, at a selected scattering angle, the scattered light intensity of the plasma. The concentration of platelets in the plasma is then determined using a computer program. (See, for example, Col. 2, lines 6-29.)

The method of Bonner differs from the method of the present claims for at least the reason that it involves determining a scattered light intensity of *non-aggregated platelets* contained in a transfusion bag, rather than an absorbance of an *analyte* in a blood bag. The term "analyte" is defined within the present specification on page 13, line 13, as a chemical component, and may include hemoglobin, bilirubin, biliverdin, Intralipid™, methylene blue, cross-linked hemoglobin, and other analytes. There is no

teaching or suggestion in Bonner that the disclosed method may be used to determine the concentration of an analyte in a blood bag as claimed in the present invention. Furthermore, an absorbance value of a plasma sample cannot be used to determine the concentration of platelets in a plasma sample according to the method of Bonner, as the method of Bonner uses a computer program that requires a scattered light intensity value. Additionally, the method of Bonner involves periodic agitation of the blood within the blood bag during a measurement cycle in order to ensure that the concentration of non-aggregated platelets is determined. (See Col. 2, lines 30-32.) Such a step is not required for the determination of an analyte in blood bag according to the presently claimed invention.

Applicant submits that Claims 1-4 and 6-8 are, therefore, novel over Bonner, and respectfully requests that the rejection of Claims 1-4 and 6-8 under 35 U.S.C. 102(b) be withdrawn. Furthermore, Applicant submits that the features of Claim 1 are not suggested in Bonner, and that one of skill in the art would not have been directed to the presently claimed methods upon reading of Bonner, as there is no suggestion that the absorbance of an analyte may be determined. Therefore, it is also submitted that Claim 1, and the claims that depend from Claim 1, are not obvious in view of Bonner.

#### **Rejections under 35 U.S.C. 103**

Claim 5 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Bonner (U.S. Patent No. 4,522,494) in view of Weythman (U.S. Patent No. 4,128,830). Applicant respectfully traverses this rejection for the reason set forth below.

As argued above, the method of Bonner differs from the method of the present claims. For example, the method of Bonner involves determining platelet concentration using scattered light intensity of a sample contained in a transfusion bag, rather than the concentration of an analyte using absorbance. There is no suggestion in Bonner that the concentration of an analyte may be determined by measuring


absorbance. This deficiency of Bonner is not remedied by combination with Weythman, which discloses compensating a signal for light sensors. There is no disclosure or suggestion in Weythman of determining the concentration of an analyte in a blood bag by measuring absorption.

Applicant further submits that Claim 5 depends from Claim 1, and therefore incorporates the features of Claim 1, none of which are disclosed or suggested by Bonner and Weythman, either alone or in combination. The claims of this application are, therefore, inventive over the combination of Bonner and Weythman, and Applicant respectfully requests that this rejection of Claim 5 under 35 U.S.C. 103(a) be withdrawn.

In view of the amendments and remarks set forth above, Applicant submits that this application is in condition for allowance, and respectfully requests prompt issuance of a notice thereof.

Applicant's undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

  
\_\_\_\_\_  
Attorney for Applicant  
Dawn C. Hayes  
Registration No. 44,751

PATENT ADMINISTRATOR  
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Chicago, Illinois 60661-3693  
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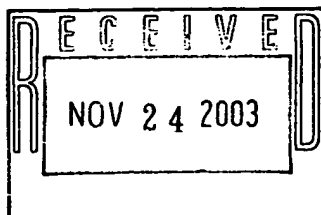
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/056,205	01/28/2002	James Samsoundar	213202.00361	6872

27160 7590 11/18/2003

PATENT ADMINSTRATOR  
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525 WEST MONROE STREET  
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CHICAGO, IL 60661-3693



EXAMINER

BROWN, KHALED

ART UNIT PAPER NUMBER

2877

DATE MAILED: 11/18/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>DOCKETED</b>	
CMID	
Action Type	<i>Politeness to Reverse</i>
Duc/Final Dates	<i>12-18-03</i>
Atty	<i>JPB</i>
Sec	
Docketed by	<i>UPE</i>
Date	<i>11-25-03</i>

